MEMORANDUM



Public Health Service Food and Drug Administration Center for Drug Evaluation and Research

DATE:

December 21, 2005

FROM:

Acting Director

Acting Director

Division of Nonprescription Regulation Development

Office of Nonprescription Products

SUBJECT:

Public Administrative File for Over-the-Counter Phenylpropanolamine-

Containing Drug Products; Tentative Final Monograph (Docket No.

1976N-0052N, formerly 1976-052N)

TO:

Division of Dockets Management (HFA-350)

Under cover of this memorandum, we are forwarding Volume No. 04PPATFM to be added to the public administrative file for the Tentative Final Monograph for Phenylpropanolamine-Containing Drug Products for Over-the-Counter Human Use. The volume includes new references cited in the tentative final monograph that are not currently included in the public administrative file.

If there are any questions, the contact person on my staff is Robert Sherman at 301-796-0996.

Susan S. Johnson, Ph.D.